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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/034,500

12/20/2001

A.A.C. Jacobs

2000.605 US

1240

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7590

07/02/2004

AKZO NOBEL PHARMA PATENT DEPARTMENT
29160 INTERVET LANE
MILLSBORO, DE 19966

EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

10/034,500

Applicant(s)

JACOBS ET AL.

Examiner

Padmavathi v Baskar

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 May 04&6/15/04 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): see attached action.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see the attached action.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.Claim(s) objected to: NONE.Claim(s) rejected: 9, 13, 18- 21 and 38.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: Examiner's advisory action and Interview Summary 6/7/04

Advisory Action

1. Applicant's after final amendment filed on 5/18/04 and supplemental amendment filed on 6/15/04 is acknowledged.

Status of claims

2. Claims 9, 19, 20 and 21 have been amended,
Claims 9, 13, 18- 21 and 38 are pending in the application and are under prosecution.

Claim Rejections - 35 USC § 112, first paragraph withdrawn

3. In view of amendment to the claims and arguments of record, the rejection of claims 9, 13, 18-21 and 38 under 35 U.S.C. 112, first paragraph, written description rejection is withdrawn.

4. In view of amendment to the claims and arguments of record, the rejection of claims 9, 13, 18-21 and 38 under 35 U.S.C. 112, first paragraph is withdrawn.

Claim Rejection - 35 USC § 102 withdrawn

5. In view of amendment to the claims, the rejection claims 9, 13, 18-21 and 38 under 35 U.S.C. 102(a) as being anticipated by Smith et al 2000 Infection and Immunity Vol. 68, No. 12 6737-6743, Vol. 68, No. 12 is withdrawn.

Claim Rejections - 35 USC § 112, second paragraph maintained

6. The rejection of claims 18 and 38 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

Applicant states that both claims are dependent on claim 9, claim 9 is directed to an isolated *Lawsonia intracellularis* outer membrane protein. This has to be the protein to which the dependent claims are directed.

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The examiner understands that the claims are dependent on claim 9. However, recitation of "a protein" does not appear to be claiming the protein of claim 9. Therefore, it is proper to recite "the protein" in the claim.

Claim Rejections - 35 USC § 102maintained

7. The rejection of claims 9, 13, 18-21 and 38 under 35 U.S.C. 102(b) as being anticipated by McOrist, S., Boid, R. and Lawson, G. H. K. 1989. Infect. Immun. 57: 957- 962 is maintained.

McOrist et al disclose Campylobacter-like organism (later designated as *L. intracellularis* bacteria) isolated from homogenized intestinal tissue of three pigs and bacteria was cultivated, intracellular bacteria was extracted, whole cell suspension was used to prepare immunogen for raising monoclonal antibodies (page 957-958 under Materials and Methods). Sonicated outer membrane antigens were separated by SDS-PAGE analysis and immunoblotted using monoclonal antibodies. Outer membrane proteins ranging from 25KD- 43 KD were identified (figure 2) as specific for Campylobacter-like organism, also now known as *L. intracellularis*. Thus the prior art disclosed outer membrane proteins read on the claimed invention because the outer membrane proteins ranging from 25KD- 43 KD contain 37KD protein. Applicant's use of the open-ended term "comprising" in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on the isolated outer membrane protein which inherently comprises the amino acid sequence as set forth in the SEQ.ID.NO: 2 including immunogenic fragments of said protein. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art outer membrane proteins and the claimed protein are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed isolated protein with the proteins of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant states that the claimed outer membrane protein having a molecular weight of about 37kD is neither anticipated nor rendered obvious by McOrist et al because Figure 2 and the other figures presented in this publication show various isolated proteins for the Campylobacter-like organism, none of which is a 37kD band and second column on page 959 stated "The protein profiles of the Campylobacter-like organism extracted from porcine proliferative enteropathy tissue were dominated by major protein bands of 55,000 and 70,000

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molecular weight. Minor components were recognized between 20,000 and 43,000, including two distinct bands at 25,000 and 27,000". Therefore, the rejection should be withdrawn.

The examiner disagrees with the applicant because claim 9 does not recite that the protein is purified. In consideration of the discrepancies often encountered in the art between protein molecular weights when determined by different methods, the 43 kD proteins disclosed by the prior art contains 37kD protein under denaturing conditions. Therefore, whenever a molecular weight is recited to characterize a protein the claim should include not only the method by which it was determined, e.g. whether by sodium dodecyl sulphate polyacrylamide gel electrophoresis, gel filtration or some other method, but also whether the determination was made under denaturing or non-denaturing conditions and whether reducing or non-reducing conditions were used. Therefore, minor components that were recognized between 20,000 and 43,000 would contain 37KD protein along with other 25kD and 27kD protein.

Remarks

8. No claims are allowed.


Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (571) 272-0853. The examiner can normally be reached on Monday through Friday from 6:30 A.M. to 4:00 P.M. EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Padma Baskar Ph.D.

6/22/04


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